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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,623	08/19/2003	Janos Szamosi	AM100224 P1	4463
25291	7590	01/21/2010	EXAMINER	
WYETH LLC			SHEIKH, HUMERA N	
PATENT LAW GROUP				
5 GIRALDA FARMS			ART UNIT	PAPER NUMBER
MADISON, NJ 07940			1615	
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			01/21/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/643,623	Applicant(s) SZAMOSI ET AL.	
	Examiner Humera N. Sheikh	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 October 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-38 and 40 is/are pending in the application.
- 4a) Of the above claim(s) 15-31 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 38 and 40 is/are allowed.
- 6) ☒ Claim(s) 32 and 34-36 is/are rejected.
- 7) ☒ Claim(s) 33 and 37 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Status of the Application

Receipt of the Response after Non-Final Office Action, the Amendment and Applicant's Arguments/Remarks, all filed 10/08/09 is acknowledged.

Applicant has overcome the following objection(s) and rejection(s) by virtue of the amendment to the claims and/or persuasive remarks: (1) The claim objection for claim 38 has been withdrawn; (2) The 35 U.S.C. 112, first paragraph rejection of claims 32 and 36 has been withdrawn; (3) The 35 U.S.C. 112, second paragraph rejection of claims 32, 34, 36 and 39 has been withdrawn; (4) The 35 U.S.C. 103(a) rejection of claims 32-39 over Mizumoto *et al.* (U.S. Pat. No. 5,576,014) in view of Mauger *et al.* (U.S. Pat. No. 5,728,403) has been withdrawn.

Claims 15-38 and 40 are pending in this action. Claims 32-34, 36 and 38 have been amended. New claim 40 has been added. Claim 39 has been cancelled herein. Claims 1-14 were previously cancelled. Claims 15-31 remain withdrawn (based on non-elected invention). Claims 32 and 34-36 are rejected. Claims 33 and 37 are objected to. Claims 38 and 40 are allowed.

* * * * *

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 32 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described

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in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 32 recites "...wherein the said fast dissolve granulation consists essentially of some or all of said one saccharide...". The limitation of "some or all of said one saccharide" constitutes new matter. While the limitation of "a portion of the saccharide" is supported, Examiner cannot find ample support for "*some or all*" of said one saccharide. Applicant is requested to identify where in the specification support for this added limitation can be found.

* * * * *

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 32 and 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shimizu *et al.* (U.S. Patent No. 6,299,904).

Shimizu *et al.* ('904) teach a solid preparation, which is a tablet, having fast disintegration that comprises (i) a pharmaceutically active ingredient; (ii) one or more water-soluble sugar alcohols selected from the group consisting of sorbitol, maltitol, reduced starch saccharide, xylitol, reduced palatinose and erythritol and (iii) low-substituted hydroxypropylcellulose (see Abstract); (col. 1, lines 8-57); (Claims 1 & 6). Two or more water-soluble sugar alcohols can be used as a mixture in a given ratio (col. 4, line 66 – col. 5, line 2).

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Lubricants are disclosed in the composition and include: sucrose fatty acid ester, polyethylene glycol, talc, stearic acid, etc. Polyethylene glycol can be used in an amount of 0.01 to 10 weight parts (col. 6, lines 26-34).

Additives are disclosed in the composition and include: artificial sweeteners such as aspartame, flavorants, lubricants, colorants, stabilizers, disintegrators, etc. (col. 5, line 59 – col. 6, line 25).

The tablets have a hardness of about 2 to about 20 kg (col. 8, lines 5-8). Applicant's recite a hardness of "less than 1.5 kp". It is the position of the Examiner that the hardness level now claimed (less than 1.5 kp) does not render a patentable distinction over the tablet of Shimizu. The determination of suitable or effective hardness levels are within the level of one of ordinary skill in the art, obtained via routine optimization. Moreover, Applicant has not demonstrated any unexpected results over the hardness now claimed.

The instant invention would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made given the teachings of Shimizu. Shimizu teaches a fast-disintegrating tablet comprising the same ingredients as claimed (drug, sugar alcohol/saccharide, polyethylene glycol (low melting point compound) whereby the tablets exhibit a suitable hardness. The reference teaches that their tablet exhibits excellent buccal disintegration and dissolution in combination with an appropriate strength or hardness and thus provides for ease of processing during manufacture.

* * * * *

Response to Arguments

Applicant's arguments filed 10/08/09 have been fully considered and were found to be partially persuasive.

▪ **Claim Objection:**

Applicant argued, “The typographical error regarding the word “flavor” has been corrected”. This was persuasive. Accordingly, the claim objection has been withdrawn.

▪ **Claim Rejections - 35 USC § 112, first and second paragraph:**

Applicant argued, “Claims 32 and 36 have been amended to more clearly define the saccharides that are contemplated in the claimed invention and to specify that the defined excipients themselves can contain no saccharides.”

This was found persuasive based on the amendment to the claims. Accordingly, the 35 U.S.C. 112, first paragraph rejection of claims 32 and 36 has been withdrawn.

Applicant argued, “Independent claims 32 and 36 have been amended to more broadly claim 'one or more' low melting point compounds and to provide the antecedent basis that Examiner pointed out was lacking. Claim 39 has been cancelled with respect to ‘consisting of’ language.”

This was found persuasive based on the amendment to the claims. Accordingly, the 35 U.S.C. 112, second paragraph rejections of claims 32, 34, 36 and 39 has been withdrawn.

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▪ **35 U.S.C. §103(a) rejection over Mizumoto et al. ('014) in view of Mauger et al. ('403):**

Applicant argued, "The current claim amendments unequivocally specify that the claimed compositions consist of a single saccharide. In contrast to Applicant's invention, Mizumoto neither suggests or teaches that a single saccharide is required (Mizumoto requires at least two saccharides with specified moldabilities) or that a water soluble excipient in combination with a low melting point solid forms a fast dissolving granulation. Mizumoto stresses the importance of having both a low and high moldability saccharides present and teaches that they should be granulated together to get the best characteristics of each. Mauger also does not disclose or suggest a combination including only a single saccharide. Mauger provides no teaching, suggestion or motivation to use a single saccharide even in the coating disclosed in Mauger much less any other capacity"

Applicant's arguments were found persuasive. Accordingly, the 35 U.S.C. 103(a) rejection of claims 32-39 over Mizumoto *et al.* in view of Mauger *et al.* has been withdrawn.

▪ **35 U.S.C. §103(a) rejection over Shimizu et al. ('904):**

Applicant argued, "The hardness range claimed by Applicants is substantially lower than the range of 2-20 kg of Shimizu. None of the Shimizu examples have a hardness that comes closed to the recited lower boundary of 2 kg. Tablet hardness may impact a number of properties of a tablet, including processability, robustness and dissolution behavior."

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This argument was not persuasive. It remains the position of the Examiner that the instant hardness of “less than 1.5 kP” is not so far from and does not distinguish over the hardness range disclosed by Shimizu (2-20 kg), which would also be considered a suitable hardness level. Moreover, the determination of suitable or effective hardness levels are within the level of one of ordinary skill in the art, obtained via routine optimization. Furthermore, no unexpected results have been observed which would accrue over the hardness level now claimed by Applicant. Applicant’s argument that the “lowest hardness actually exemplified in Shimizu is 4.2 kg in Working Example 5” was not persuasive since the prior art is not limited to the specific working examples exemplified therein, but rather, the art is considered, as a whole, for what it teaches to one skilled in the art. Applicant’s argument regarding properties affected by hardness was not persuasive. In response to applicant's argument that the references fail to show certain features of applicant’s invention, it is noted that the features upon which applicant relies (i.e., processability, robustness and dissolution behavior) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Furthermore, the prior art teaches a combination of the same elements provided in a similar fashion as that instantly claimed, and thus, it would be expected that the properties imparted by those elements would also be the same as that sought by Applicant.

Applicant argued, “Nowhere does Shimizu disclose or suggest the combination of a single saccharide and a low melting point compound to form a fast dissolving granulation comprising about 30% to about 75% of the tablet weight.”

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This argument was not deemed persuasive. Shimizu teaches a solid preparation – a tablet that has fast disintegration and that comprises a combination of an active ingredient, *one* or more water-soluble sugar alcohols (implying a single saccharide can be used) as well as ingredients such as polyethylene glycol. The polyethylene glycol disclosed would be a suitable low melting point compound. Regarding Applicant's argument that "Shimizu does not recognize the advantage of a low melting point compound", this was not convincing since "[T]he fact that appellant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious." *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). With regards to the instant amounts of the fast dissolving granulation (about 30% to about 75% of the tablet weight), the Examiner points out that differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The instant amounts claimed do not establish a patentable distinction over the explicit teachings of the art, which recognizes and teaches the same ingredients employed by Applicant.

This rejection of record has been maintained.

Allowable Subject Matter

Claims 38 and 40 are allowed.

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Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Claims 38 and 40 are allowed.

Claims 33 and 37 are objected to.

Claims 32 and 34-36 are rejected.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday-Friday during regular business hours.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax, can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Humera N. Sheikh/

Primary Examiner, Art Unit 1615

hns

January 17, 2010

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